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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,763	09/09/2003	Richard J. Daignault JR.	02-006 CON	4848

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ADVANCED NEUROMODULATION SYSTEMS, INC.  
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EXAMINER

SAJOUS, WESNER

ART UNIT PAPER NUMBER

2628

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/659,763

Applicant(s)

DAIGNAULT, RICHARD J.

Examiner

Sajous Wesner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-33,35,36 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-29 is/are allowed.
- 6) ☒ Claim(s) 20-23,30-33 and 35 is/are rejected.
- 7) ☒ Claim(s) 36,41 and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

This communication is responsive to the amendment and response dated March 20, 2007. Claims 20-36 and 40-42 are presented for examination, of which claims 40-42 are newly added.

#### ***Allowable Subject Matter***

1. The indicated allowability of claims 20-23 is withdrawn in view of the newly discovered reference(s) to North et al. (US 20040059395). Rejections based on the newly cited reference(s) follow.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 20-23 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by the North et al. (US 20040059395).

Considering claims 20-23, North discloses a database structure comprising a first field (30, fig. 4A) operable for identifying a subject (see paragraphs 96 and 156); a second field corresponding to a first region of an object representation having a plurality of predetermined regions, the object representation representing at least a portion of a human body (see fig. 7A), wherein the second field is [intrinsically] operable for storing

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(e.g., via an on-screen buffer inherently provided in the screen display) a first value (e.g., a threshold or amplitude level) representing one of a plurality of conditions of a first type (e.g., stimulation amplitude level for sensation of pain, see paragraphs 162-163, 178 and 181); and a second value (e.g., a threshold or amplitude level) representing one of a plurality of conditions of a second type (e.g., degree of pain, see paragraphs 168-169, 178 and 181). See also paragraphs 157 and 177, which suggests that the screen is used to collect (or store) the data inputted for each stimulation and pain entry level for further analysis. See paragraphs 185-190, 197, 200, which suggest that the entered amplitude thresholds representing the body regions types or pain level can be set at zero (see paragraph 188) or at less than a maximum (paragraph 189); the pain rating procedure is determined on a numerical scale (paragraph 153). The stimulation setting during analysis is sorted and displayed in ranked by threshold amplitude value, scaled threshold amplitude value, pain relief chosen threshold (see paragraph 198-203). See further paragraphs 205-208 and paragraphs 220-232, wherein the body stimulation threshold or body pain areas corresponds to pain type value; pain rating corresponds to pain depth; and pain level corresponds to pain intensity.

Considering claim 40, the limitations recited in claim 40 are analogous to the limitations recited in claims 20-23, respectively. As the limitations of claims 20-23 have been anticipated by the teaching of North, it is readily apparent that the applied prior art performs the underlying elements. As such, the limitations of claim 40, is, therefore, rejected under the same rationale as claims 20-23, respectively. In particular, North

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discloses, at figs. 4-10, a system (24, fig. 5) for managing data relevant to pain experienced by one or more patients, comprising: a processor (25, fig. 5) for controlling the system; a display (30, fig. 4) for displaying information to a user of the system; one or more input controls (31, 37, 41, & 59) for obtaining data from the user; software (see paragraph 26 or 108) defining one or more applications for obtaining and storing data relevant to pain experienced by one or more patients, the software operable to display one or more representations of at least a portion of a human body, wherein the representation includes a plurality of regions (see fig. 7); processing first and second data from a user (see paragraphs 153, 157, 162-163, 178, 181, 200-232); and a store data (38, fig. 5) identifying the selected regions and the first and second attributes values (see paragraphs 111-113, 124).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Applicant's Admitted Prior Art (AAPA) in view of North et al. (US 20040059395).

Considering claims 30-33, the AAPA discloses means for associating at least two conditions to a first region (e.g., neck or back region) of an object representation

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represented by a plurality of regions (e.g., dermatome regions) and representing at least a portion of a human body (see fig. 1 of AAPA); and means for generating a representation of the at least two conditions associated to the first region in a distinguishable manner from each other for graphical representation on a display, wherein the at least two conditions are related to attributes of pain, wherein a first condition related to pain intensity (or pain value or amount of pain) and a second condition related to pain type (e.g., chronic pain or dermatome related data of human body); and a third condition related to pain depth (e.g., afflicted nervous tissue). See paragraphs 6-8.

The AAPA fails to teach the plurality of conditions is graphically represented by a color and a graphical pattern.

North teaches body pain conditions graphically represented by a color (see paragraph 180) and a graphical pattern (e.g., region outlining, see paragraphs 148-149 and 180).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the features of the AAPA to include the plurality of conditions is graphically represented by a color and a graphical pattern, in the same conventional manner as taught by North; in order to allow the physician to effectively distinguish the different body region conditions or pain types during analysis of the patient's body stimulation.

As per claim 34, the AAPA, at fig. 2 depicts one of the plurality of conditions is graphically representable by a color (e.g., via item 102') and another of the plurality of

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conditions is graphically representable by a graphical pattern (e.g., remaining portions of the body).

As per claim 35, the AAPA, at fig. 2 depicts each of the plurality of regions that is static in position and is independent of any overlapping regional boundaries of any adjacent regions.

### ***Allowable Subject Matter***

5. Claims 24-29 are allowed over the prior art because they fail to teach a database structure configured for storing a record, the structure comprises a second field corresponding to a first region of an object representation having a plurality of predetermined regions, the object representation representing at least a portion of a human body, wherein the second field is operable for storing: a first value representing one of a plurality of conditions of a first type, and a second value representing one of a plurality of Conditions of a second type (as recited in claim 20). The prior art fail also to teach a database structure comprises a third database table that comprises data for associating the third database table with a first and a second database tables, and a map having a plurality of fields corresponding to a plurality of regions associated with an object representation representing at least a portion of a human body, each of the plurality of fields operable for storing a first condition value and a second condition value to particularly define a first attribute and a second attribute associated with the corresponding region (as recited in claim 24).

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6. Claims 36 and 41-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, because the prior art of record fail to teach means for generating a representation of at least two conditions associated to first region representing a portion of a human body in a distinguishable manner from each other for graphical representation on a display, wherein one of the plurality of conditions is graphically representable by a color and another of the plurality of conditions is graphically representable by a graphical pattern; and a means for converting graphical representations of regions and any associated conditions into a non graphical information form for storage (as recited in claim 36). The prior art fail also to teach a system for managing data relevant to pain experienced by one or more patients wherein a software is operable to:

(v) retrieve the stored data identifying the selected region or regions and the first and second attribute values; and

(vii) generate a representation of at least a portion of a human body that includes one or more regions visually identifying respective pain intensities and physical sensation pain types in the one or more regions (as recited in claim 41).

The software stores data identifying the selected regions and the first and second attribute values in a multi-patient database (as recited in claim 42).



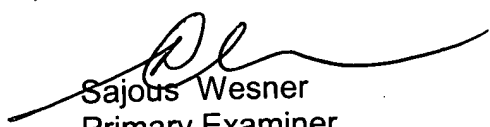
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**Conclusion**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sajous Wesner whose telephone number is 571-272-7791. The examiner can normally be reached on M-F 9:15-6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Razavi can be reached on 571-272-7664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Sajous Wesner  
Primary Examiner  
Art Unit 2628

WS  
4/10/07